

## PART 602—EPIDEMIOLOGY AND OTHER HEALTH STUDIES FINANCIAL ASSISTANCE PROGRAM

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### APPENDIX A TO PART 602—SCHEDULE OF RENEWAL APPLICATIONS AND REPORTS

AUTHORITY: 42 U.S.C. 2051; 42 U.S.C. 5817; 42 U.S.C. 5901–5920; 42 U.S.C. 7254 and 7256; 31 U.S.C. 6301–6308.

SOURCE: 60 FR 5841, Jan. 31, 1995, unless otherwise noted.

#### § 602.1 Purpose and scope.

This part sets forth the policies and procedures applicable to the award and administration of grants and cooperative agreements by DOE (through the Office of Environment, Safety and Health or any office to which its functions are subsequently redelegated) for health related research, education/training, conferences, communication, and related activities.

#### § 602.2 Applicability.

(a) This part applies to all grants and cooperative agreements awarded after the effective date of this rule.

(b) Except as otherwise provided by this part, the award and administration of grants and cooperative agreements shall be governed by 10 CFR part 600 (DOE Financial Assistance Rules).

#### § 602.3 Definitions.

In addition to the definitions provided in 10 CFR part 600, the following definitions are provided for purposes of this part:

*Conference and communication activities* means scientific or technical conferences, symposia, workshops, seminars, public meetings, publications, video or slide shows, and other presentations for the purpose of communicating or exchanging information or views pertinent to DOE.

*DOE* means the United States Department of Energy.

*Education/Training* means support for education or related activities for an individual or organization that will enhance educational levels and skills, in particular, scientific or technical areas of interest to DOE.

*Epidemiology and Other Health Studies* means research pertaining to potential health effects resulting from DOE or predecessor agency operations or from any aspect of energy production, transmission, or use (including electromagnetic fields) in the United States and abroad. Related systems or activities to enhance these areas, as well as other program areas that may be described by notice published in the FEDERAL REGISTER, are also included.

*Principal investigator* means the scientist or other individual designated by the recipient to direct the project.

*Research* means basic and applied research and that part of development not related to the development of specific systems or products. The primary aim of research is scientific study and experimentation directed toward advancing the state of the art or increasing knowledge or understanding rather than focusing on a specific system or product.

#### § 602.4 Deviations.

(a) Single-case deviations from this part may be authorized in writing by the Assistant Secretary for Environment, Safety and Health, the Head of the Contracting Activity, or their designees, upon the written request of DOE staff, an applicant for award, or a recipient. A request from an applicant or a recipient must be submitted to or through the cognizant contracting officer.

(b) Whenever a proposed deviation from this part would be a deviation from 10 CFR part 600, the deviation must also be authorized in accordance

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with the procedures prescribed in that part.

### § 602.5 Epidemiology and Other Health Studies Financial Assistance Program.

(a) DOE may issue under this part awards for research, education/training, conferences, communication, and related activities in the Office of Environment, Safety and Health program areas set forth in paragraph (b) of this section.

(b) The program areas are:

- (1) Health experience of DOE and DOE contractor workers;
- (2) Health experience of populations living near DOE facilities;
- (3) Workers exposed to toxic substances, such as beryllium;
- (4) Use of biomarkers to recognize exposure to toxic substances;
- (5) Epidemiology and other health studies relating to energy production, transmission, and use (including electromagnetic fields) in the United States and abroad;
- (6) Compilation, documentation, management, use, and analysis of data for the DOE Comprehensive Epidemiologic Data Resource; and
- (7) Other systems or activities enhancing these areas, as well as other program areas as may be described by notice published in the FEDERAL REGISTER.

### § 602.6 Eligibility.

Any individual or entity other than a Federal agency is eligible for a grant or cooperative agreement. An unaffiliated individual is also eligible for a grant or cooperative agreement.

### § 602.7 Solicitation.

(a) The Catalog of Federal Domestic Assistance number for 10 CFR part 602 is 81.108 and its solicitation control number is EOHSFAP 10 CFR part 602.

(b) An application for a new or renewal award under this solicitation may be submitted at any time to DOE at the address specified in paragraph (c) of this section. New or renewal applications shall receive consideration for funding generally within 6 months but, in any event, no later than 12 months from the date of receipt by DOE.

(c) Except as otherwise provided in a notice of availability, applicants may obtain application forms, described in 602.8(b) of this part, and additional information from the Office of Epidemiology and Health Surveillance (EH-42), U.S. Department of Energy, Washington, DC 20585, (301) 903-5926, and shall submit applications to the same address.

(d) DOE will publish program notices in the FEDERAL REGISTER regarding the availability of epidemiology and other health studies financial assistance. DOE may also use other means of communication, as appropriate, such as the publication of notices of availability in trade and professional journals and news media.

(1) Each notice of availability shall cite this part and shall include:

(i) The Catalog of Federal Domestic Assistance number and solicitation control number of the program;

(ii) The amount of money available or estimated to be available for award;

(iii) The name of the responsible DOE program official to contact for additional information and an address where application forms may be obtained;

(iv) The address for submission of applications; and

(v) Any evaluation criteria in addition to those set forth in § 602.9 of this part.

(2) The notice of availability may also include any other relevant information helpful to applicants such as:

(i) Program objectives;

(ii) A project agenda or potential area of project initiatives;

(iii) Problem areas requiring additional effort; and

(iv) Any other information that identifies areas in which grants or cooperative agreements may be made.

(e) DOE is under no obligation to pay for any costs associated with the preparation or submission of applications.

(f) DOE reserves the right to fund, in whole or in part, any, all, or none of the applications submitted.

(g) To be considered for a renewal award under this part, an incumbent recipient shall submit a continuation or renewal application, as provided in § 602.8 (c) and (h) of this part.

**§ 602.8 Application requirements.**

(a) An original and seven copies of the application for initial support must be submitted, except that State and local governments and Indian tribal governments shall not be required to submit more than the original and two copies of the application.

(b) Each new or renewal application in response to this part must include:

(1) An application face page, DOE Form 4650.2 (approved by OMB under OMB Control No. 1910–1400). However, the face page of an application submitted by a State or local government or an Indian tribal government shall be the face page of Standard Form 424 (approved by OMB under OMB Control Number 0348–0043).

(2) A detailed description of the proposed project, including its objectives, its relationship to DOE's program, its impact on the environment, if any, and the applicant's plan for carrying it out.

(3) Detailed information about the background and experience of the recipients of funds or, as appropriate, the principal investigator(s) (including references to publications), the facilities and experience of the applicant, and the cost-sharing arrangements, if any.

(4) A detailed budget for the entire proposed period of support with written justification sufficient to evaluate the itemized list of costs provided on the entire project. Applicants should note the following when preparing budgets:

(i) Numerical details on items of cost provided by State and local government and Indian tribal government applicants shall be on Standard Form 424A, "Budget Information for Non-Construction Programs" (approved under OMB Control No. 0348–0044). All other applicants shall use budget forms ERF 4620.1 (approved by OMB under Control No. 1910–1400).

(ii) DOE may, subsequent to receipt of an application, request additional budgetary information from an applicant when necessary for clarification or make informed pre-award determinations under 10 CFR part 600.

(5) Any pre-award assurances required pursuant to 10 CFR parts 600 and 602.

(c) Applications for a renewal award must be submitted with an original and seven copies, except that State and

local governments and Indian tribal government applicants are required to submit only an original and two copies (Approved by OMB under OMB Control Numbers 0348–00050348–0009.)

(d) The application must be signed by an official who is authorized to act for the applicant organization and to commit the applicant to comply with the terms and conditions of the award, if one is issued, or if unaffiliated, by the individual applicant. (See § 602.17(a)(1) for requirements on continuation awards.)

(e) DOE may return an application that does not include all information and documentation required by statute, this part, 10 CFR part 600, or the notice of availability, when the nature of the omission precludes review of the application.

(f) During the review of a complete application, DOE may request the submission of additional information only if the information is essential to evaluate the application.

(g) In addition to including the information described in paragraphs (b), (c), and (d) of this section, an application for a renewal award must be submitted no later than 6 months before the expiration of the project period and must be on the same forms as required for initial applications. The renewal application must outline and justify a program and budget for the proposed project period, showing in detail the estimated cost of the proposed project, together with an indication of the amount of cost sharing, if any. The application shall also describe and explain the reasons for any change in the scope or objectives of the proposed project and shall compare and explain any difference between the estimates in the proposed budget and actual costs experienced as of the date of the application.

(h) DOE is not required to return an application to the applicant.

(i) Renewal applications must include a separate section that describes the results of work accomplished through the date of the renewal application and how such results relate to the activities proposed to be undertaken in the renewal period.

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### § 602.9 Application evaluation and selection.

(a) Applications shall be evaluated for funding generally within 6 months, but in any event no later than 12 months, from the date of receipt by DOE. After DOE has held an application for 6 months, the applicant may, in response to DOE's request, be required to revalidate the terms of the original application.

(b) DOE shall perform an initial evaluation of all applications to ensure that the information required by this part is provided, that the proposed effort is technically sound and feasible, and that the effort is consistent with program funding priorities. For applications that pass the initial evaluation, DOE shall review and evaluate each application received based on the criteria set forth below and in accordance with the Office of Environment, Safety and Health Merit Review System developed, as required, under DOE Financial Assistance Regulations, 10 CFR part 600.

(c) DOE shall select evaluators on the basis of their professional qualifications and expertise. To ensure credible and inclusive peer review of applications, every effort will be made to select evaluators apart from DOE employees and contractors. Evaluators shall be required to comply with all applicable DOE rules or directives concerning the use of outside evaluators.

(d) DOE shall evaluate new and renewal applications based on the following criteria that are listed in descending order of importance:

- (1) The scientific and technical merit of the proposed research;
- (2) The appropriateness of the proposed method or approach;
- (3) Competency of research personnel and adequacy of proposed resources;
- (4) Reasonableness and appropriateness of the proposed budget; and
- (5) Other appropriate factors consistent with the purpose of this part established and set forth in a Notice of Availability or in a specific solicitation.

(e) DOE shall also consider as part of the evaluation other available advice or information, as well as program policy factors, such as ensuring an appro-

priate balance among the program areas listed in § 602.5 of this part.

(f) In addition to the evaluation criteria set forth in paragraphs (d) and (e) of this section, DOE shall consider the recipient's performance under the existing award during the evaluation of a renewal application.

(g) Selection of applications for award will be based upon the findings of the technical evaluations (including peer reviews, as specified in the Office of Environment, Safety and Health Merit Review System), the importance and relevance of the proposal to the Office of Environment, Safety and Health's mission, and the availability of funds. Cost reasonableness and realism will also be considered.

(h) After the selection of an application, DOE may, if necessary, enter into negotiations with an applicant. Such negotiations are not a commitment that DOE will make an award.

### § 602.10 Additional requirements.

(a) A recipient performing research or related activities involving the use of human subjects must comply with DOE regulations in 10 CFR part 745, "Protection of Human Subjects," and any additional provisions that may be included in the special terms and conditions of an award.

(b) A recipient performing research involving recombinant DNA molecules and/or organisms and viruses containing recombinant DNA molecules shall comply with the National Institutes of Health "Guidelines for Research Involving Recombinant DNA Molecules" (51 FR 16958, May 7, 1986), or such later revision of those guidelines, as may be published in the FEDERAL REGISTER. (The guidelines are available from the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room BBB, Bethesda, MD 20892, or from the Office of Epidemiology and Health Surveillance, (EH-42), U.S. Department of Energy, Washington, DC 20585).

(c) A recipient performing research on warm-blooded animals shall comply with the Federal Laboratory Animal Welfare Act of 1966, as amended (7 USC 2131 et seq.), and the regulations promulgated thereunder by the Secretary

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of Agriculture at 9 CFR chapter I, subchapter A, pertaining to the care, handling, and treatment of warm-blooded animals held or used for research, teaching, or other activities supported by Federal awards. The recipient shall comply with the guidelines described in the Department of Health and Human Services Publication No. [NIH] 86-23, "Guide for the Care and Use of Laboratory Animals," or succeeding revised editions. (This guide is available from the Office for Protection from Research Risks, Office of the Director, National Institutes of Health, Building 31, Room 4B09, Bethesda, MD 20892, or from the Office of Epidemiology and Health Surveillance, (EH-42), U.S. Department of Energy, Washington, DC 20585).

### § 602.11 Funding.

(a) The project period during which DOE expects to provide support for an approved project under this part shall generally not exceed 3 years and may exceed 5 years only if DOE makes a renewal award or otherwise extends the award. The project period shall be specified on the Notice of Financial Assistance Grant (DOE Form 4600.1).

(b) Each budget period of an award under this part shall generally be 12 months and may be as much as 24 months, as DOE deems appropriate.

### § 602.12 Cost sharing.

Cost sharing is not required, nor will it be considered, as a criterion in the evaluation and selection process unless otherwise provided under § 602.9(d)(5).

### § 602.13 Limitation of DOE liability.

Awards made under this part are subject to the requirement that the maximum DOE obligation to the recipient is the amount shown in the Notice of Financial Assistance Award as the amount of DOE funds obligated. DOE shall not be obligated to make any additional, supplemental, continuation, renewal, or other award for the same or any other purpose.

### § 602.14 Fee.

(a) Notwithstanding 10 CFR part 600, a fee may be paid, in appropriate circumstances, to a recipient that is a small business concern, as qualified

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under the criteria and size standards of 13 CFR part 121, in order to permit the concern to participate in the Epidemiology and Other Health Studies Financial Assistance Program. Whether or not it is appropriate to pay a fee shall be determined by the contracting officer, who shall, at a minimum, apply the following guidelines:

(1) Whether the acceptance of an award will displace other work that the small business is currently engaged in or committed to assume in the near future; or

(2) Whether the acceptance of an award will, in the absence of paying a fee, cause substantial financial distress to the business. In evaluating financial distress, the contracting officer shall balance current displacement against reasonable future benefit to the company. (If the award will result in the beneficial expansion of the existing business base of the company, then no fee would generally be appropriate.) Fees shall not be paid to other entities except as a deviation from 10 CFR part 600, nor shall fees be paid under awards in support of conferences.

(b) To request a fee, a small business concern shall submit with its application a written self-certification that it is a small business concern qualified under the criteria and size standards in 13 CFR part 121. In addition, the application must state the amount of fee requested for the entire project period and the basis for requesting the amount and must also state why payment of a fee by DOE would be appropriate.

(c) If the contracting officer determines that payment of a fee is appropriate under paragraph (a) of this section, the amount of fee shall be that determined to be reasonable by the contracting officer. The contracting officer shall, at a minimum, apply the following guidelines in determining the fee amount:

(1) The fee base shall include the estimated allowable cost of direct salaries and wages and allocable fringe benefits. This fee base shall exclude all other direct and indirect costs.

(2) The fee amount expressed as a percentage of the appropriate fee base, pursuant to paragraph (c)(1) of this section, shall not exceed the percentage

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rate of fee that would result if a Federal agency contracted for the same amount of salaries, wages, and allocable fringe benefits under a cost reimbursement contract.

(3) Fee amounts, determined pursuant to paragraphs (c)(1) and (c)(2) of this section, shall be appropriately reduced when:

(i) Advance payments are provided; and/or

(ii) Title to property acquired with DOE funds vests in the recipient (10 CFR part 600).

(d) Notwithstanding 10 CFR part 600, any fee awarded shall be a fixed fee and shall be payable on an annual basis in proportion to the work completed, as determined by the contracting officer, upon satisfactory submission and acceptance by DOE of the progress report. If the project period is shortened due to termination, or the project period is not fully funded, the fee shall be reduced by an appropriate amount.

### § 602.15 Indirect cost limitations.

Awards issued under this part for conferences and scientific/technical meetings will not include payment for indirect costs.

### § 602.16 National security.

Activities under the Epidemiology and Other Health Studies Financial Assistance Program are not expected to involve classified information (i.e., Restricted Data, Formerly Restricted Data, National Security Information). However, if in the opinion of the recipient or DOE such involvement becomes expected prior to the closeout of the award, the recipient or DOE shall notify the other in writing immediately. If the recipient believes any information developed or acquired may be classified, the recipient shall not provide the potentially classified information to anyone, including DOE officials with whom the recipient normally communicates, except the Director of Declassification, and shall protect such information as if it were classified until notified by DOE that a determination has been made that it does not require such handling. Correspondence that includes the specific information in question shall be sent by registered mail to the U.S. Department of Energy, Attn: Di-

rector of Declassification, NN-50, Washington, DC 20585. If the information is determined to be classified, the recipient may wish to discontinue the project, in which case the recipient and DOE shall terminate the award by mutual agreement. If the award is to be terminated, all material deemed by DOE to be classified shall be forwarded to DOE in a manner specified by DOE for proper disposition. If the recipient and DOE wish to continue the award, even though classified information is involved, the recipient shall be requested to obtain both personnel and facility security clearances through the Office of Safeguards and Security for Headquarters awards or from the cognizant field office Division of Safeguards and Security for awards obtained through DOE field organizations. Costs associated with handling and protecting any such classified information shall be negotiated at the time that the determination to proceed is made.

### § 602.17 Continuation funding and reporting requirements.

(a) A recipient shall periodically report to DOE on the project's progress in meeting the project objectives of the award. The following types of reports shall be used:

(1) *Progress Reports.* After issuance of an initial award, recipients must submit a satisfactory progress report to receive a continuation award for the remainder of the project period. The original and two copies of the required report must be submitted to the Office of Environment, Safety and Health program manager 90 days prior to the anticipated continuation funding date. The report should include results of work to date and emphasize findings and their significance to the field, and any real or anticipated problems. The report also should contain the following information: On the first page, provide the project title, principal investigator/project director name, period of time the report covers, name and address of recipient organization, DOE award number, the amount of unexpended funds, if any, that are anticipated to be left at the end of the current budget period. If the amount exceeds 10 percent of the funds available

for the budget period, provide information as to why the excess funds are anticipated to be available and how they will be used in the next budget period. The report should state whether the aims have changed from the original application, and if they have, provide revised aims. A completed budget page must be submitted with the continuation progress report when a change to anticipated future costs will exceed 25 percent of the original recommended future budget.

(2) *Notice of Energy Research and Development (R&D) Project.* A Notice of Energy R&D Project, DOE Form 1430.22, which summarizes the purpose and scope of the project, must be submitted in accordance with the Distribution and Schedule of Documents set forth in Appendix A to this part, Schedule of Renewal Applications and Reports. Copies of the form may be obtained from a DOE contracting office.

(3) *Special Reports.* The recipient shall report the following events to DOE as soon after they occur as possible:

(i) Problems, delays, or adverse conditions that will materially affect the ability to attain project objectives or prevent the meeting of time schedules and goals. The report must describe remedial action that the recipient has taken, or plans to take, and any action DOE should take to alleviate the problems.

(ii) Favorable developments or events that enable meeting time schedules and goals sooner, or a lower cost than anticipated, or producing more beneficial results than originally projected.

(4) *Final Report.* A final report covering the entire project must be submitted by the recipient within 90 days after the project period ends or the award is terminated. Satisfactory completion of an award will be contingent upon the receipt of this report. The final report shall follow the same outline as progress reports. Recipients will provide, as part of the final report, a description of records and data compiled during the project, along with a plan for its preservation or disposition (see § 602.19 of this part). All manuscripts prepared for publication should be appended to the final report.

(5) *Financial Status Report (FSR)* (OMB No. 0348–0039). The FSR is re-

quired within 90 days after completion of each budget period. For budget periods exceeding 12 months, an FSR is also required within 90 days after this first 12 months unless waived by the contracting officer.

(b) DOE may extend the deadline date for any report if the recipient submits a written request before the deadline, that adequately justifies an extension.

(c) A table summarizing the various types of reports, time for submission, and number of copies is set forth in appendix A to this part. The schedule of reports shall be as prescribed in this table, unless the award document specifies otherwise. These reports shall be submitted by the recipient to the awarding office.

(d) DOE, or its authorized representatives, may make site visits, at any reasonable time, to review the project. DOE may provide such technical assistance as may be requested.

(e) Recipients may place performance reporting requirements on a sub-recipient consistent with the provisions of this section.

#### § 602.18 Dissemination of results.

(a) Recipients are encouraged to disseminate research results promptly. DOE reserves the right to utilize, and have others utilize to the extent it deems appropriate, the reports resulting from research awards.

(b) DOE may waive the technical reporting requirement of progress reports set forth in § 602.17, if the recipient submits to DOE a copy of its own report that is published or accepted for publication in a recognized scientific or technical journal and that satisfies the information requirements of the program.

(c) Recipients are urged to publish results through normal publication channels in accordance with the applicable provisions of 10 CFR part 600.

(d) The article shall include an acknowledgement that the project was supported, in whole or in part, by a DOE award, and specify the award number, but state that such support does not constitute an endorsement by DOE of the views expressed in the article.

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### § 602.19 Records and data.

(a) In some cases, DOE will require submission of certain project records or data to facilitate mission-related activities. Recipients, therefore, must take adequate steps to ensure proper management, control, and preservation of all project records and data.

(b) Awardees must ensure that all project data is adequately documented. Documentation shall:

(1) Reference software used to compile, manage, and analyze data;

(2) Define all technical characteristics necessary for reading or processing the records;

(3) Define file and record content and codes;

(4) Describe update cycles or conditions and rules for adding or deleting information; and

(5) Detail instrument calibration effects, sampling and analysis, space and time coverage, quality control measures, data algorithms and reduction methods, and other activities relevant to data collection and assembly.

(c) Recipients agree to comply with designated DOE records and data management requirements, including providing electronic data in prescribed formats and retention of specified records and data for eventual transfer to the Comprehensive Epidemiologic Data Resource or to another repository, as directed by DOE. Recipients will provide, as part of the final report, a description of records and data compiled during the project along with a plan for its preservation or disposition.

(d) Recipients agree to make project records and data available as soon as possible when requested by DOE.

#### APPENDIX A TO PART 602—SCHEDULE OF RENEWAL APPLICATIONS AND REPORTS

Type	When due	Number of copies for awarding office
1. Summary: 200 words on scope and purpose (Notice of Energy R&D Project).	Immediately after a grant is awarded and with each application for renewal.	3
2. Renewal period ends .....	6 months before the budget .....	8
3. Progress Report period (or as part of a renewal application).	90 days prior to the next budget period .....	3
4. Other progress reports, brief topical reports, etc. (Designated when significant results develop or when work has direct programmatic impact).	As deemed appropriate by DOE or the recipient .....	3
5. Reprints, Conference .....	Same as 4. above .....	3
6. Final report of the project .....	Within 90 days after completion .....	3
7. Financial Status Report (FSR) .....	Within 90 days after completion of the project period; for budget periods exceeding 12 months an FSR is also required within 90 days after the first 12-month period.	3

**Note:** Report types 5 and 6 require with submission two copies of DOE Form 1332.16, University-Type Contractor and Grant-ee Recommendations for Disposition of Scientific and Technical Document.

## PART 605—THE OFFICE OF ENERGY RESEARCH FINANCIAL ASSISTANCE PROGRAM

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#### APPENDIX A TO PART 605—ENERGY RESEARCH PROGRAM OFFICE DESCRIPTIONS

**AUTHORITY:** Section 31 of the Atomic Energy Act, as amended, Pub. L. 83-703, 68 Stat. 919 (42 U.S.C. 2051); sec. 107 of the Energy Reorganization Act of 1974, Pub. L. 93-438, 88 Stat. 1240 (42 U.S.C. 5817); Federal Non-nuclear Energy Research and Development